



TYPE A - PACKAGING

**SAFE TRANSPORTATION OF PET
RADIOPHARMACEUTICALS
BY ROAD, SEA AND AIR**



VON GAHLEN
FOR SURE



Every year, 20 million shipments of radioactive material take place by land, sea and air. A huge part of these shipments consist of medical isotopes. Every day, patients rely on safe transport of the nuclear medicine they require for their treatment. It goes without saying that the process of getting the medical isotope from the production facility to the patient needs to be flawless.

Radiopharmaceuticals shipped by air, sea or road transport must be enclosed in certified Type A containers. Type A packaging is an international regulation issued by the International Atomic Energy Agency (IAEA), to assure the safety of both the radiopharmaceuticals and the people that are involved in the transportation of the radiopharmaceuticals.

CHALLENGES WHEN SHIPPING RADIOACTIVE MATERIALS

To decide which method of transport and type of packaging is suitable for your needs mostly depends on two things: the half-life time of the medical isotope you want to ship and the length of the journey. For example, F18 or FDG is mostly shipped domestically by road, so over shorter distances. Z89 can also be shipped internationally by air, due to the longer half-life time compared to F18.

Challenges when it comes to the packaging of radioactive materials are process specific requirements, depending on how the isotope is produced. The transport index (TI) for packages is used to control radiation exposure and is derived from the maximum dose equivalent rate at one meter from the surface of a package containing radioactive material. The value of the TI restricts the transportation of a single package and the sum of multiple packages in a single shipment. Labelling and marking requirements are depending on the applicable regulations.



RADIOPHARMACEUTICAL PACKAGING SOLUTIONS THAT FIT YOUR NEEDS

The standard range of Type A packaging that is offered by Von Gahlen is the result of a close collaboration with our customers. Based on their wishes and demands, these products evolved into a standard solution over the past 20 years. For the remaining requirements, that relate to the product, shipping conditions and the production process, we can develop a tailor-made solution together.

Our shielding packaging solutions are made to protect people against the radiation emitted by radiopharmaceuticals. At the same time, our tungsten containers and lead containers ensure that bottles, syringes and capsules containing radioactive substances such as F18, iodine, Lutetium and Gallium are protected against external influences.



TYPE A PACKAGING FOR MEDICAL ISOTOPES

For both domestic and international transportation we offer a standardized solution: Type A lead and tungsten containers. Our type A packaging consists of multiple components which ensure safe shipment of radiopharmaceuticals. We offer disposable and non-disposable packaging for single or multiple type A containers. You can reuse our non-disposable packaging, while our single-use disposable packaging is easy to use and designed to be as cost-effective as possible. All our packaging solutions have an optimal integration with the hot cells we build for nuclear medicine & radiopharmacy. The type A containers can be used with our product retrieval drawer with auto capping function to provide you with a shielded solution for your finished radiopharmaceutical.

TYPE A PACKAGE WITH LEAD CONTAINER

Designed for the safe transport of high energy gamma (PET) radiopharmaceuticals in vials by road, air, sea and inland waterways.

- ① Re-usable complete Type A package
- ① Two packaging options for road transportation: a plastic container or a flight case
- ① Tested and certified according to IAEA regulations for the Safe Transport of Radioactive Material SSR-6



TYPE A PACKAGE WITH TUNGSTEN CONTAINER

Our premium solution for high energy gamma (PET) radiopharmaceuticals in vials for long distances by road, air, sea and inland waterways.

- ① Re-usable complete Type A package
- ① Comes with heavy duty flight case
- ① Tested and certified according to IAEA Regulations for the Safe Transport of Radioactive Material SSR-6





TAILOR-MADE TYPE A PACKAGING FOR AN OPTIMAL INTEGRATION IN YOUR PRODUCTION PROCESS

Since every radiopharmaceutical product is unique, with its own production process and therefore different packaging and transport requirements, sometimes we need to start from the ground up to ensure your product is transported in a safe way. That's why we also create packaging from a blank sheet of paper to a fully developed and approved tailor-made packaging solution. We have a standard project approach and design procedure, which we use to design our hot cell applications as well.

We'll start with creating a User Requirement Specification (URS). This document consists of all your wishes and requirements. The more accurately this information is documented, the better the results. This phase is also important because the type of packaging has a big impact on the transportation process. Because many parties are involved, it affects the entire chain. For example, we'll always advise you to involve your specialized supplier for transport of radioactive material in the development of new packaging.

Typical topics we discuss at the start of the design process are:

- ① What is the starting activity?
- ① What is the dose rate at the outside of the packaging or transport index?
- ① Number of doses in one shipping package to determine the optimal volume to be shipped?
- ① What is the optimal storage volume of every component?
- ① Way of transportation by air, road or both?
- ① Temperature control required during shipment?
- ① Exact labeling requirements?
- ① Is water resistance needed?
- ① Requirements to use a certain material?



FUNCTIONAL DESIGN AND TESTING PROCEDURE

Next step is to create a Functional Design Specification (FDS), a document in which our solution matches up to your requirements. After the design is approved, we'll make a 3D printed prototype on actual scale. This allows you to see the design in real life, with the actual dimensions. This will also tackle any unforeseen design flaws. When the prototype is approved, the detailed design is made digitally. In this phase, all the details needed to start producing the first series will be clear. Once the required quantities and delivery schedules are made, we can start manufacturing the first series and do the predetermined and mandatory tests. The testing procedure can be different in each case, however there are guidelines to determine the test we need to execute.

Examples of these tests are:

- 🌀 Drop tests
- 🌀 Penetration tests
- 🌀 Temperature profile tests
- 🌀 Stacking tests
- 🌀 Internal pressure tests of the container

AN OPTIMIZED PACKAGING PROCESS

Subsequently, we also provide a service to optimize your radiopharmaceutical packaging process. We analyze your existing process and the type of packaging you're using to see if there is room for any improvements. Important aspects for us to look at are disposables, determining the optimal buffer quantities and optimizing the needed storage volume. Also the choice for a single or repeated usage - either as part of the packaging or the complete packaging in itself - affects the solution. With single-use packaging, the product costs are more important, while for the re-usable parts, the wear can be more important. As a designer and manufacturer of both re-useable and single-use packaging we can help you with a suitable solution.

For a customer with a very high product output, we designed a tailor-made solution for a higher output capacity. In this application more type A containers can be pre-loaded using a conveyor system, this results in a faster and more efficient product output.





STANDARD AND CUSTOM-BUILT SOLUTIONS FOR NUCLEAR MEDICINE AND RADIOPHARMACY

Von Gahlen is a family owned business with over 45 years of experience in developing radiation shielding solutions. Without making concessions in quality and reliability, we ensure that everything exactly fits your needs. We continually refine and enhance proven techniques, based on newly gathered insights. That's how we develop and build products to offer protection for people, their working environment and the radiopharmaceuticals they produce.

Our products offer protection during the production of radiopharmaceuticals for diagnostics and treatment, such as hot cells, glove boxes and fume hoods. We supply University Medical Centers, hospitals, research institutions and commercial pharmacies that are handling nuclear medicine. One of our specialties is the production and worldwide supply of radiopharmaceutical packaging for shipping by road or air. Together with you, we develop the most durable and safest solutions. For sure!



WHAT IS YOUR CHALLENGE?

Thank you for your interest and your time. We would welcome the opportunity to meet with you and discuss the challenges you come across in your daily work. Please feel free to contact us if you have some questions about this article, our products or the optimization of your packaging process. We will gladly think along with you!

[Share your challenge with us](#)



VON GAHLEN
FOR SURE

WWW.VONGAHLEN.COM